## REMARKS

In view of the following remarks responsive to the Office Action of February 10, 2004, Applicant respectfully requests favorable reconsideration of this application.

Claims 1-18 are pending in this application. Claims 19-26 have been withdrawn from consideration in view of the previous restriction requirement.

Applicant respectfully thanks the Office for the indication that claims 14-16 are merely objected to as depending from a base claim but would be allowable if rewritten in that form.

The remaining claims, claims 1-13, 17, and 18, have been rejected as obvious over the combination of Gomez and Alt.

The present invention pertains to a stent delivery system particularly adapted to assure that the stent is not moved by the delivery apparatus in the body lumen inadvertently during the implantation process. Particularly, the stent delivery mechanism comprises a catheter having an outer tube and an inner tube designed to hold the stent therein in a radially constricted condition by one or more inflatable balloons carried on the inner tube at or near the location of the loaded stent. More specifically, the stent is positioned between the outer surface of an inner tube and the inner surface of the outer tube. The balloon or balloons may be axially aligned with the stent, i.e., the stent is mounted over the balloons on the inner tube.

For implantation, the assembly is inserted into the body lumen with the outer tube essentially protecting the stent. The outer tube and inner tube are not

moved relative to each other during this positioning. When the entire assembly is positioned so that the stent is in the desired deployment position, the balloon is inflated to an internal pressure or volume that is small enough so that the frictional force between the balloon and the inner surface of the outer tube is not so great that it is impossible or difficult to slide the outer tube relative to the inner tube and balloons yet is high enough to keep the stent from moving with respect to the inner tube when the outer tube is slid relative to the inner tube of the balloon. The outer tube is then withdrawn, thereby exposing the stent to the vessel. The balloon should be formed of a material that is more compliant than the outer tube so that the balloon will take a greater set against the stent than it will against the outer tube, thus holding the balloon in place longitudinally relative to the inner tube when the outer tube is moved longitudinally.

**The Gomez Reference**

Gomez discloses a method of delivering a self-expanding stent wherein a balloon is positioned at the end of a tube and the stent is crimped to the balloon. The crimping attaches the stent to the balloon tightly enough so that it is unlikely that the stent will move axially relative to the balloon. When the catheter has been advanced over the guide wire 18 so that the stent and balloon are at the deployment site, the balloon is then expanded to cause the stent to expand to meet the walls of the body lumen. The balloon is deflated, and the catheter and guide wire are then removed, leaving the stent in place. There is no outer tube to protect the stent during the advancement of the catheter to its point of site in

Gomez. The stent completely exposed within the body lumen during insertion of the catheter. It is held fixed to the catheter by crimping it to the balloon.

**The Alt Reference**

Alt discloses the same system for delivering a stent as Gomez. Particularly, the Office's assertion to the contrary notwithstanding, Alt does not disclose the step of inflating the balloon so as to trap the stent between the balloon and the outer tube. Alt does differ from Gomez in that it does describe that the axial length of the balloon is greater than the axial length of the stent so that the balloon axially extends both proximally and distally of the stent. Alt further discloses the step of the slightly inflating balloon to a pressure low enough that it does not expand the stent that is crimped to the balloon, but so that the proximal and distal ends of the balloon that extend beyond the axial extremes of the stent do expand to a diameter greater than the stent. This radial expansion of the proximal and distal ends of the balloon beyond the radial diameter of the stent further helps assure that the stent cannot slide longitudinally on the balloon during advancement. However, in Alt, just as in Gomez, there is no outer tube at all. The balloon does not contact an outer tube in Alt. There is no outer tube.

Accordingly, all claims as currently pending patently distinguish over Gomez or Alt taken individually or in combination. Fundamentally, neither reference discloses an outer tube and, therefore, cannot possibly meet the limitations of the claims.

Referring to independent claim 1, for instance, the prior art of record does not disclose "providing a stent delivery device comprising an outer tube . . . sized to hold the said stent therein" or that the balloon is "positioned within said outer tube". It also does not disclose "positioning said stent in a radially constricted state within said outer tube," also as claimed in claim 1. The prior art further does not disclose "inflating said balloon so as to trap said stent between said balloon and said outer tube", also as claimed in claim 1.

Finally, the prior art does not disclose "moving said outer tube proximally relative to said inner tube, said balloon and said stent." Obviously, the prior art of record cannot meet any of these limitations since it does not disclose an outer tube.

All other claims depend upon claim 1 and, therefore, distinguish over the prior art of record for at least all of the reasons discussed above in connection with claim 1.

In addition, note that at least dependent claims 2, 8, and 13 recite further limitations concerning steps performed in connection with the outer tube. Since the prior art of record does not disclose an outer tube, these limitations obviously also cannot be met by the prior art.

In addition, claim 18 depends from claim 1 and adds the limitation that step 1 comprises providing an inflation tube separate from the inner tube. This is not taught in either Gomez or Alt.

In view of the foregoing amendments and remarks, this application is now in condition for allowance. Applicant respectfully requests the Examiner to

issue a Notice of Allowance at the earliest possible date. The Examiner is invited to contact Applicant's undersigned counsel by telephone call in order to further the prosecution of this case in any way.

Respectfully submitted,

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